UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,032	12/06/2000	Bryan Paul Morgan	WN/KH/JJ/WCM	7516

7590 11/01/2002

Young & Thompson
Second Floor
745 South 23rd Street
Arlington, VA 22202

EXAMINER	
GUNTER, DAVID R	

ART UNIT	PAPER NUMBER
1634	4

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,032	MORGAN ET AL.	
	Examiner	Art Unit	
	David R. Gunter	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/6/00* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Traversal

In paper number 13, received July 13, 2002, the applicants elected with traverse SEQ ID NO:17. The traversal was on the grounds that there was no undue search burden involved in searching SEQ ID NOS: 17-19 simultaneously. This argument is not found persuasive.

As stated in the restriction requirement dated May 6, 2002 (paper number 12), polynucleotides with different nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, and are therefore subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. Furthermore, because SEQ ID NOS: 17-19 differ in their amino acid sequences, they require three separate searches to identify polynucleotides that encode each of the three distinct amino acid sequences. This represents a significant search burden for the examiner and the office, and therefore the restriction requirement is still deemed proper and is made **final.**

Claims 1-17, claims 19-33, and SEQ ID NOS: 18-19 are withdrawn from consideration as not directed to the elected subject matter.

Objections

1. The title is not descriptive of the subject matter and must be changed to more accurately reflect the subject matter, e.g. "Putative Porcine Homolog of Human Decay-Accelerating Factor."

2. The figures contain multiple deficiencies, outlined on form PTO-948, Notice of Draftperson's Patent Drawing Review. Correction of the deficiencies is required.

3. The specification refers to polynucleotide and polypeptide sequences by the name of the encoded protein or by the sequence without referring to a Sequence ID Number. For example, the description of figure 15 found on page 16 of the specification does not indicate which of the sequences listed in the figure correspond to SEQ ID NOS: 17-19. All sequences in the specification must be referred to by their SEQ ID Number.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 18 is drawn to "a DNA molecule selected from ... a pig DAF gene ... [or] a genomic DNA corresponding to [a pig DAF gene]." The terms "gene" and "genomic DNA" read on the native DNA sequence found within the chromosome of an animal. The claim does not recite terms such as "isolated" or "purified," which would indicate the "hand of the inventor." As such, the claim reads on a product of nature and is non-statutory subject matter.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Claim 18 is drawn to "a DNA molecule selected from ... a pig DAF gene ... [or] a genomic DNA corresponding to [a pig DAF gene]." The term "pig DAF gene" is not limited to Decay Accelerating Factor. In addition to being an acronym for Decay Accelerating Factor, DAF is also the name of a transcription factor homologous to forkhead-family transcription factors AFX, FKHRL1, and FKHR (Yoko, et al, Journal of Biological Chemistry 277:26729-26732, 2002). The specification provides no disclosure of the sequence, structure, or function of this transcription factor, nor is there a known or disclosed correlation between the described sequence of the pig DAF gene and the sequence, structure, or function of the DAF transcription factor. One skilled in the art would not recognize from the disclosure that the applicant was in possession of the gene for the DAF transcription factor or genomic DNA corresponding to the DAF transcription factor.

b. Claim 18 is drawn to "a DNA molecule selected from ... a pig DAF gene ... [or] a genomic DNA corresponding to [a pig DAF gene]." As broadly as claimed, the terms "gene" and "genomic DNA" read on not only the DNA which encodes pig DAF, but also

introns, 5' and 3' untranslated regions, enhancers, promoters, and other regulatory elements. The specification provides no disclosure of any of these elements. There is no known or disclosed correlation between the described sequences of the pig DAF gene and the sequence or structure or the non-described regulatory elements and untranslated regions of the gene.

Furthermore, the meaning of the phrase "corresponding to" a pig DAF gene is not clear. The term "corresponding" may refer to a physical correspondence between unrelated genes that are located in close proximity on a single chromosome, to a regulatory correspondence between a gene and cis- or trans- acting regulatory sequences, a functional correspondence between a gene and other genes that encode proteins with similar activity, or an evolutionary correspondence between genes that arose by duplication of a common ancestor. The specification provides no disclosure of any of these elements.

c. Claim 18 further recites "a DNA molecule ... substantially homologous to, or capable of hybridizing to a substantial portion" a pig DAF gene. The meaning of the term "substantial portion" is not clear because the specification does not define how large a fragment of the gene must be to be considered "substantial." As broadly as claimed, a portion of the gene could represent as little as a single nucleotide or as much as the entire length of the gene including all of the gene's regulatory, non-coding, and non-translated elements.

The meaning of the phrase "a sequence substantially homologous to" is also unclear. As described above, the specification does not teach a size above which a

portion of the gene is considered to be substantial. In addition, the specification does not teach a specific degree of similarity that must be present between a nucleotide sequence and a portion of the DAF gene for the two molecules to be considered homologous. If the degree of similarity necessary for two molecules to be considered homologous is low enough, and if the portion of the DAF gene is small enough (e.g. four nucleotides), the claim as written potentially reads on any nucleic acid sequence. The specification does not provide adequate disclosure of sufficient embodiments to adequately describe the broad genus upon which the claim language reads.

In a similar manner, the meaning of the phrase "a sequence ... capable of hybridizing to a substantial portion of a gene defined in (a) above" is unclear. As described above, the specification does not teach a size above which a portion of the gene is considered to be substantial. In addition, the specification does not teach the conditions under which hybridization will take place, and therefore the stringency of the hybridization conditions is unknown. Under conditions of sufficiently low stringency, any nucleic acid sequence can be induced to hybridize with the DAF gene. The specification does not provide adequate disclosure of sufficient embodiments to adequately describe the broad genus upon which the claim language reads.

d. Claim 18 is drawn to "a DNA molecule ... substantially homologous to, or capable of hybridizing to a substantial portion" a pig DAF gene. As outlined in items a-c above, the terms "DAF," "substantially homologous," "capable of hybridizing," and "substantial portion" are all undefined terms which each encompass a very broad genus of nucleic acid sequences. The sequences include mutants, variant, homologs, analogs,

orthologs, and genomic sequences from any source. The specification does not provide adequate disclosure of sufficient embodiments to adequately describe any of the broad genera upon which the claim language reads.

Even if read in the most narrow terms, the claim still reads on a very broad genus of nucleic acid molecules. DNA molecules which have a high degree of homology to, or are capable of hybridizing under stringent conditions to, the entire gene for porcine Decay Accelerrating Factor would encode a broad range of proteins of varying homology to the polypeptide sequence of SEQ ID NO: 17.

The specification teaches several clones of putative porcine homologs to human Decay Accelerating Factor. All are taught to be identical through the signal peptide and first three short consensus repeats (SCRs), but all diverge thereafter (page 43, lines 11-17). One of these clones, pDAF-7 is taught to contain 3 SCRs, a serine/threonine/proline-rich region (STP), and a carboxy-terminal sequence which may encode a glycolipid anchor or membrane anchor (page 43, lines 20-25). The specification further teaches that when the first three SCRs are fused to Fc and expressed in Chinese Hamster Ovary cells, the fusion protein inhibits the activity of complement (page 44, lines 6-13).

Beyond demonstrating that the first three SCR domains are sufficient to convey complement-inhibiting activity, the specification offers no teaching which correlate the sequence of pDAF-7 to its function. The specification does not teach which amino acids within the pDAF-7 protein are necessary for its function. Nor does it teach how to modify the sequence of pDAF-7 to obtain any specific homolog. It is not clear which

positions with the pDNA-7 molecule can be substituted or altered without resulting in a loss of the function of the pDAF-7 protein. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule encodes a protein that is functionally equivalent to pDAF-7 or a protein that is unrelated to pDAF-7, or to determine which DNA molecules satisfy the definition of "substantially homlogous" to a DAF gene and which are unrelated DNA molecules.

Although the specification does also teach the clone identified as pDAF-14, the teaching of one additional member of the genus of putative porcine Decay Accelerating Factor homologs does not adequately describe the genus. pDAF-14 is a partial sequence and does not represent a complete open reading frame. In addition, there is no sequence analysis of the domains present in pDAF-14, and no demonstrated sequence alignment of pDAF-14 to pDAF-7. There is therefore no basis for comparison between the two sequences, and a skilled artisan would be unable to demonstrate the presence of conserved amino acid residues which might suggest a correlation between the structure and function of the pDAF clones.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of an isolated polynucleotide encoding the polypeptide of SEQ ID NO:17, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polynucleotide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claim 30.

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding the polypeptide of SEQ ID NO: 17, does not reasonably provide enablement for "a pig DAF gene, a DNA molecule ... substantially homologous to, or capable of hybridizing to a substantial portion" a pig DAF gene, genomic DNA corresponding to a pig DAF gene, or a fragment of any of these molecules. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As outlined above, the terms "DAF," "gene," "genomic DNA," "corresponding to," "substantially homologous," "capable of hybridizing," "substantial portion," and fragment are all undefined terms which each encompass a very broad genus of nucleic acid sequences. "DAF" is both an acronym for Decay Accelerating Factor and also the name of a transcription factor homologous to forkhead-family transcription factors AFX, FKHRL1, and FKHR (Yoko, et al, Journal of Biological Chemistry 277:26729-26732, 2002). "Gene" and "genomic DNA" read on not only the DNA which encodes pig DAF, but also introns, 5' and 3' untranslated regions, enhancers, promoters, and other regulatory elements. The term "corresponding" may refer to a physical correspondence between unrelated genes that are located in close proximity on a single chromosome, to a regulatory correspondence between a gene and cis- or trans- acting regulatory sequences, a functional correspondence between a gene and other genes that encode proteins with similar activity, or an evolutionary correspondence between genes that arose by duplication of a common ancestor. In the absence of a definition in the specification, a "substantial portion" of a gene could represent as little as a single nucleotide or as much as the entire length of the gene including all of the gene's regulatory, non-coding, and non-translated elements.

The specification offers no definition of the term "homologous." If the degree of similarity necessary for two molecules to be considered homologous is set low enough, and if the "substantial portion" of the DAF gene is small enough (e.g. four nucleotides), the claim as written potentially reads on any nucleic acid sequence. The specification further offers no definition of the phrase "capable of hybridizing" and teaches no specific hybridization condtions.

Under conditions of sufficiently low stringency, any nucleic acid sequence can be induced to hybridize with the DAF gene.

Finally, the specification does not teach how large or small of segment of the claimed nucleic acids must be in order to be considered a "fragment of a molecule." As broadly as claimed, the fragment of a DNA molecule could read on a single nucleotide, or a single carbon atom. Therefore, as broadly as written, claim 18 reads on any nucleic acid sequence, any single nucleotide, ribose sugars, phosphate groups, or a single carbon atom.

The specification teaches several clones of putative porcine homologs to human Decay Accelerating Factor including pDAF-7 and pDAF-14, which are taught to be identical through the signal peptide and first three short consensus repeats (SCRs), but all diverge thereafter (page 43, lines 11-17). The recitation of these sequences, however, does not enable the skilled artisan to make or identify any "substantial" homolog or any sequences that hybridize to a substantial portion of the DNA encoding any pig DAF gene, nor would it allow the skilled artisan to make or identify genomic DNA corresponding to a pig DAF gene. pDAF-7 is taught to contain 3 SCRs, a serine/threonine/proline-rich region (STP), and a carboxy-terminal sequence which may encode a glycolipid anchor or membrane anchor (page 43, lines 20-25). Although the specification teaches that when the first three SCRs are fused to Fc and expressed in CHO cells the fusion protein inhibits the activity of complement (page 44, lines 6-13), the specification offers no guidance as to which amino acids are critical to the function of the SCR domains, or how the other identified domains function to give pDAF-7 its activity.

The specification does not teach how to modify the sequence of pDAF-7 to obtain any specific homolog. It is not clear which positions with the pDNA-7 molecule can be substituted

or altered without resulting in a loss of the function of the pDAF-7 protein. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule encodes a protein that is functionally equivalent to pDAF-7 or a protein that is unrelated to pDAF-7, or to determine which DNA molecules satisfy the definition of "substantially homlogous" to a DAF gene and which are unrelated DNA molecules without undue experimentation.

The sequence of pDAF-14 is also taught in the specification, however pDAF-14 is a partial sequence and does not represent a complete open reading frame. There is no sequence analysis of the domains present in pDAF-14, and no demonstrated sequence alignment of pDAF-14 to pDAF-7. There is therefore no basis for comparison between the two sequences, and a skilled artisan would be unable to demonstrate the presence of conserved amino acid residues which might suggest a correlation between the structure and function of the pDAF clones.

A correlation between the protein of SEQ ID NO: 17 and the proteins encoded by the broad range of nucleic acid molecules recited in claim 18 is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to pig DAF. Since neither the specification nor the art teach the specific amino acid residues responsible for the biological function or activity of the polypeptide of SEQ ID NO 17, for example within the SCR domains, nor how the skilled artisan could modify a specific amino acid within the polypeptide of SEQ ID NO 17 to obtain a polypeptide with either retained or modified activity, the skilled artisan would be required to perform undue experimentation to make or use the polynucleotides that encode biologically active or altered polypeptides encompassed by the broadly claimed invention.

To practice the invention as broadly as it is claimed, the skilled artisan would first have to isolate every nucleic acid encompassed by claim 18, translate these nucleic acids into polypeptides, and then determine whether or not the encoded polypeptide has activity similar to that reported for Decay Accelerating Factor. Given that the art teaches that a single amino acid change can alter the function of a biomolecule and that some of these changes are unpredictable, such analyses would require trial and error, thus constituting undue experimentation.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 18 (b), the claim recites "a sequence substantially homologous to, or capable of hybridizing to, a substantial portion of a gene defined in (a) above."

1) The term "capable of" is indefinite because the meaning of the term is not clear. "Capable of" is not an active method step, and may be interpreted to recite either a property of the DNA molecule or a potential method of using the DNA molecule. The claim should be amended to state that the DNA molecule "hybridizes to" the gene defined in (a) above.

2) The term "substantial portion" is indefinite because it is not clear how large a fragment of the gene must be to be considered "substantial." The

specification does not teach a specific length, above which portions of the gene are considered "substantial" and therefore the metes and bounds of the claim are not clearly defined. As broadly as claimed, a portion of the gene could represent as little as a single nucleotide or as much as the entire length of the gene including all of the gene's regulatory, non-coding, and non-translated elements.

3) The phrase "a sequence substantially homologous to ... a substantial portion of the gene defined in (a) above" is indefinite. As described above, the specification does not teach a size above which a portion of the gene is considered to be substantial. In addition, the specification does not teach a specific degree of similarity or identity that must be present between a nucleotide sequence and a portion of the DAF gene for the two molecules to be considered homologous. If the degree of similarity necessary for two molecules to be considered homologous is low enough, and if the portion of the DAF gene is small enough (e.g. four nucleotides), the claim as written potentially reads on any nucleic acid sequence. For this reason, the metes and bounds of the claims are unclear.

4) The phrase "a sequence ... capable of hybridizing to a substantial portion of a gene defined in (a) above" is indefinite. As described above, the specification does not teach a size above which a portion of the gene is considered to be substantial. In addition, the specification does not teach the conditions under which hybridization will take place, and therefore the stringency of the hybridization conditions is unknown. Under conditions of sufficiently low

stringency, any nucleic acid sequence can be induced to hybridize with the DAF gene. For this reason, the metes and bounds of the claims are unclear.

b. Regarding claim 18 (d), the claim recites "a genomic DNA corresponding to" a pig DAF gene or its complementary strand. The phrase "corresponding to" is indefinite because the meaning of "corresponding" is not clear. The term "corresponding" may refer to a physical correspondence between unrelated genes that are located in close proximity on a single chromosome, to a regulatory correspondence between a gene and cis- or trans- acting regulatory sequences, a functional correspondence between a gene and other genes that encode proteins with similar activity, or an evolutionary correspondence between genes that arose by duplication of a common ancestor. For this reason, the metes and bounds of the claim are unclear.

c. Regarding claim 18 (e), the claim recites "a fragment of a molecule defined in any of (a), (b), (c), or (d) above." The term "fragment" is indefinite because the meaning is unclear. The specification does not teach how large or small of segment of the claimed nucleic acids must be in order to be considered a "fragment of a molecule." As broadly as claimed, the fragment of a DNA molecule could read on a single nucleotide, or a single carbon atom.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Caras, et al., Nature 325(6104):545-549, 1987. (hereinafter referred to as "Caras"). Claim 18 recites a DNA molecule substantially homologous to, or capable of hybridizing to, a substantial portion of a pig DAF gene or its complementary strand. As described above in the section entitled "Claim Rejections - 35 USC § 112 Second Paragraph," the meaning of "substantial portion," "substantially homologous," and "capable of hybridizing" are unclear because they are not clearly defined in the specification. Furthermore, as described above in the section entitled "Claim Rejections - 35 USC § 112 First Paragraph," the term "pig DAF gene" is not clear because DAF is both an acronym for Decay Accelerating Factor and the name of a transcription factor. For the purpose of comparing the claim to the prior art, the elected polypeptide sequence, SEQ ID NO: 17 will be considered to be a protein encoded by a member of the genus of pig DAF genes.

Caras discloses a DNA sequence that encodes human Decay Accelerating Factor protein, which is 42% identical and 61% similar to the polypeptide sequence of SEQ ID NO: 17. Based on the degree of sequence similarity between the protein encoded by the DNA disclosed by Caras and the polypeptide of SEQ ID NO: 17, the DNA sequence disclosed by Caras is considered to be substantially homologous to and capable of hybridizing to a substantial portion of a pig DAF gene.

Conclusion

5. No claims are allowed. However, the examiner notes that a sequence search for an isolated DNA sequence encoding the polypeptide of SEQ ID NO: 17 reveals that such a DNA sequence is free from the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, Phd
October 29, 2002

JEHANNE SOUAYA
PATENT EXAMINER
Jehanne Souaya
10/30/02